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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,839	06/21/2002	Marie Flamand	03495.0213	3749

22852 7590 06/27/2003

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EXAMINER

STUCKER, JEFFREY J

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/6/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 21-40 is/are pending in the application.
- Of the above claim(s) 21-26, 31-37, 39, & 40 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 27-30 & 38 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No. 3
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

This Office Action is in response to applicant's election without traverse of Group II, claims 27-30 and 38. Claims 21-26, 31-37, 39, and 40 are withdrawn from consideration as being drawn to non-elected inventions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-30 and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-30 are indefinite because it is not clear what distinguishes the capture antibody from the revelation antibody as they are each described the same way.

Claim 38 is incomplete because there is no step of selecting the antibodies.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter

sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 27-30 are rejected under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994).

The instantly claimed invention is directed to a kit (boxed set) comprising a first antibody and a second antibody, at least one positive control and at least one negative control. The antibodies can be monoclonal or polyclonal antibodies directed against a NS1 protein. Claim 29 further limits the NS1 protein to a dengue virus NS1 protein.

It is noted that claims 28 and 30 are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2113:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of

a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The specific deposited plasmid of claim 30 is part of the process. Further, the plasmid, absent evidence to the contrary, appears to be the same as, or an obvious variant of, the known NS1 protein.

The instant specification teaches at the bottom of page 6 that a report by Falconar in 1991 discloses the development of a double antibody sandwich assay for detecting dengue NS1 protein in serum samples. The antibodies are disclosed to be polyclonal antibodies and monoclonal antibodies. The disclosure does not specify that serum NS1 is hexameric or that the components are available in kit form.

Zuk et al. teach that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (column 22, line 62 to col. 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the necessary reagents, including positive and negative controls, to

perform the immunodiagnostic assay in a kit format for the convenience and economy of the user. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for the optimization the assay for use in a clinical diagnostic laboratory or physician's office.

Because the antibodies of the Falconar method are detecting antigen in patients' sera, it would be reasonable to expect that the antibodies are binding to the hexameric form of the protein which is the secreted form of NS1. This is known in the art as taught by Crooks et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect hexameric antigens from flaviviruses in general, and dengue in particular, given their widely recognized public health risks, because one would be motivated to produce an assay kit to detect infections. Thus, the instant invention is obvious over the admissions in the specification in view of both Zuk et al. and Crooks et al.

Claim 38 is rejected under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994) further in view of Harlow et al.

Claim 38 is directed to a method for selecting specific anti-NS1 antibodies by binding the antibodies to NS1 protein in hexameric form.

The relevance of the admissions in the specification in view of Zuk et al. and Crooks et al. is set forth above. The prior art provides reasons to screen for antibodies that react with the hexameric form of NS1. Harlow et al. teach that the antibodies are affinity screened. Therefore, it would be obvious to use a known method of selecting useful antibodies to produce usable antibodies. Thus, the instant invention is obvious over the admissions in the specification in view of both Zuk et al. and Crooks et al. further in view of Harlow et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fields teaches that several immunoassays for capturing flavivirus antigens were known prior to the instant invention.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Serial Number: 09/980839
Art Unit: 1648

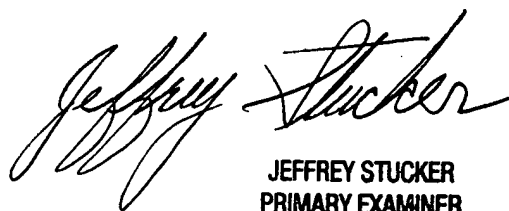
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The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center Customer Service representative whose telephone number is (703) 308-0198.



JEFFREY STUCKER
PRIMARY EXAMINER